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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,907	03/09/2004	Duran Yetkinler	SKEL-012CIP	3390

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/797,907	Applicant(s) YETKINLER ET AL.	
	Examiner Anu Ramana	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/14/05; 1/3/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1, 20 and 27 are objected to due to a minor informality. In line 1 of these claims, "using" should be "filling" and vice versa.

In claim 1, line 3, it appears that "said cement" should be "a cement" to correct a minor typographical error.

Claim 9 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5 and 10-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz et al. (US 6,149,655).

Constantz et al. disclose a method of introducing calcium phosphate cement for orthopedic applications utilizing a cement delivery means such as a needle wherein the needle is vibrated to enhance perfusion of cement (col. 25, lines 38-59, col. 27, lines 11-57, col. 28, lines 49-67 and col. 29, lines 1-67).

Regarding claim 14, Constantz et al. are utilizing vibration to enhance cement delivery. Thus, when vibration is stopped, perfusion of cement should also substantially stop.

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Claims 20-25 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito (US 6,340,299).

Saito discloses a system for delivering a cement including a delivery device or cannula or needle 35 and a vibration generating mechanism or "vibratory element" 11 for vibrating the cement delivery device (Fig. 2, col. 5, lines 11-67, col. 6, lines 37-45 and col. 7, lines 18-39).

Claim Rejections - 35 USC § 102/103

Claims 17-32 are rejected under 35 U.S.C. 102(b) as anticipated by Constantz et al. (US 6,149,655) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Constantz et al. (US 6,149,655).

Although Constantz et al. do not make an explicit reference to a vibratory element attached to the cement delivery means or needle such an element would be inherently necessary in order to vibrate the cement delivery needle.

One of ordinary skill in the art would have found it obvious to provide a vibratory element attached to the needle in order to vibrate the needle. To support this position, the Examiner directs Applicants' attention to Sproul (US 6,832,988) who discloses an ultrasonic pulse generator or "vibratory element" 92 attached to an ultrasonic probe 91 in order to vibrate the probe (Fig. 7 and col. 7, lines 15-47).

The method steps of claims 17-19 are rendered obvious by the above discussion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655), as applied to claim 1, in view of Fishburne, Jr. (US 5,639,238).

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Constantz et al. disclose all elements of the claimed invention except for the use of vibration with preparation of cement.

It is well known to vibrate a filling material to remove bubbles from the material. See col. 2, lines 34-42 of Fishburne, Jr.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have vibrated the cement or "filling material" prior to its use to remove air bubbles from the cement.

The method steps of claim 2 are rendered obvious by the above discussion.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655), as applied to claim 1, in view of Sproul (US 6,832,988).

Constantz et al. disclose all elements of the claimed invention except for the step of vibration in conjunction with preparation of a target bone site for introduction of cement.

Sproul teaches utilizing ultrasonic vibrations for maceration of diseased tissue prior to cement injection (col. 1, lines 29-38 and col. 7, lines 15-47).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized ultrasonic vibrations, as taught by Sproul, for removing diseased tissue during verteboplasty according to the method of the combination of Constantz et al. and Sproul.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655), as applied to claim 1, in view of Spiegelberg et al. (US 2002/0183851A1).

Constantz et al. disclose all elements of the claimed invention except for ultrasonic vibrations in a range of about 0.1 to 100,000 Hz.

Spiegelberg et al. teach providing ultrasonic vibrations in a range of 1 to 500 rad/sec for compaction of bone cement ([para [0019]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have vibrated the cement delivery needle with a

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frequency in a range of 1 to 1,000 rad/sec (or 0.15 to 159 Hz) for compaction of bone cement as taught by Spiegelberg et al.

The combination of Constantz et al. and Spiegelberg et al. discloses the claimed invention except for vibration frequencies in a range of 0.1 to about 100,000 Hz. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided vibration frequencies in a range of about 0.1 to about 100,000 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 21 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 18 of copending Application No. 10/661,356. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 18 discloses all elements of the claimed invention. The only difference between the claims being the intended use recitation "flowable composition" versus "cement composition" with respect to the introduction element which has been given no patentable weight.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/661,356 ('356 herein).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claims of the present application and the claims of the copending application is that the claims of the copending application include more elements and are thus more specific. Thus the invention of the claims of "356" is in effect a "species" of the "generic" invention of the claims of the present application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims of the present application are anticipated by the claims of "019", they are not patentably distinct from the claims of the copending application.

This is a provisional obviousness-type double patenting rejection.

Claims 1-6, 10-25 and 27-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/900,019 ('019 herein).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claims of the present application

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and the claims of the copending application is that the claims of the copending application include more elements and are thus more specific. Thus the invention of the claims of "356" is in effect a "species" of the "generic" invention of the claims of the present application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims of the present application are anticipated by the claims of "019", they are not patentably distinct from the claims of the copending application.

This is a provisional obviousness-type double patenting rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*
March 19, 2005

Kevin Shaver
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